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10/586,678	07/20/2006	**Kazuhiro Tanahashi**	0599-0217PUS1	8081

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

NOTIFICATION DATE	DELIVERY MODE
10/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,678	TANAHASHI ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-23* is/are allowed.

6)☒ Claim(s) *1-14 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 16 is objected to because of the following informalities: claim 16 depends from itself. Appropriate correction is required. (For examination purposes, it is presumed that claim 16 should depend from claim 15.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Vishnoi et al., 6,348,156.

Vishnoi et al. disclose a blood separation system comprising a device for separating whole blood into red blood cells and plasma, such blood separation devices being for example a membrane blood separation device (col. 6, lines 60-63.) The system includes a sensing assembly outside the device, which comprises a first sensor to sense a characteristic of plasma and a second sensor adjacent to the first sensor to sense a characteristic of red blood cells. A fluid circuit is coupled to the device and includes a plasma collection tube for conveying a flow of plasma from the device and a

red blood cell collection tube for conveying a flow of red blood cells from the device. According to this aspect of the invention, the tubes are held in a fixture, which is movable into releasable engagement with the sensing assembly. The fixture holds the plasma collection tube and the red blood cell collection tube in adjacent sensing alignment with, respectively, the first sensor and the second sensor. See column 3, lines 15-31. It is also disclosed that in one embodiment, the fluid circuit includes a whole blood inlet tube for conveying a flow of whole blood into the device. In this embodiment, the fixture also holds the whole blood inlet tube. The fixture thereby serves to gather and hold the whole blood inlet tube, the plasma collection tube, and the red blood cell collection tube in a bundle. See column 3, lines 32-37. Vishnoi et al. disclose that the system can be provided such that it maintains a closed blood processing environment (col. 10, line 63 to column 11, line 10.)

Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. See col. 12, lines 16-29.

As to claims 1 and 12, the closed system disclosed by Vishnoi et al. is equivalent to Applicant's claimed fractionation device. The whole blood inlet tube is equivalent to the claimed supply part for loading raw liquid. The chamber housing the membrane is equivalent to the claimed filtration part for filtering some of the solutes. The part of the device on the side of the membrane with the separated materials is equivalent to

Applicant's claimed concentration part for concentrating filtrate from the filtration part. The pneumatic pump is equivalent to the claimed flow pump.

As to claim 2, the plasma collection tube is equivalent to the claimed recovery part for recovering concentrated solution obtained in the concentration part.

As to claim 4, the separation membrane is equivalent to the claimed filtration apparatus.

As to claim 6, a pump as claimed is disclosed (see col. 12, lines 16-29.)

As to claim 7, the plasma collection tube is equivalent to the claimed container.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of O'Connor et al., 7,074,327.

Vishnoi et al. has been discussed above (see discussion of claim 1.) However, Vishnoi et al. do not disclose that the total inner capacity of the closed circuit is 50 mL or lower. However, microfabrication of laboratory devices is well known in the art and its benefits are also well known, as shown by O'Connor et al. in disclosing that microfluidic

technology allows for use of very small quantities and thus less liquid waste and reduced cost (col. 1, line 59 to col. 2, line 15.) It would have been obvious to one of ordinary skills in the art at the time the invention was made to scale down the size of the Vishnoi et al. system since it is well known, as shown by O'Connor et al., that providing a device on a small scale provides the benefit of reducing waste and cost. Providing the capacity in the specific range claimed by Applicant is within a workable range.

As to claim 9, the Vishnoi et al. apparatus produced on a small scale is equivalent to a cartridge.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of Komatsu et al., 5,976,433.

Vishnoi et al. has been discussed above regarding claim 1. However, Vishnoi et al. do not disclose that the filtration apparatus is a module having hollow fiber membranes.

However, Komatsu et al. disclose slit-like micropores mean micropores thinly extending in the direction of hollow fiber axis (col. 3, lines 24-33.) The PVA-based hollow fiber membranes, having sharp fractionating capability, is effective in separating different substances having close particle sizes and can be used for blood filtration and separation of plasma among other uses (col. 6, lines 53-61.)

It would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the Vishnoi et al. device by providing the hollow fiber

membranes taught by Komatsu et al. as the means for plasma separation because Komatsu et al. disclose that such material is effective in separating different substances having close particle sizes and can be used for blood filtration and separation of plasma. The skilled artisan would have had reasonable expectation of success because Vishnoi et al. do not limit the invention to only a separation matrix and thus the skilled artisan would expect that the device can be used with other plasma separating elements, such as that disclosed by Komatsu et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of Mendel-Hartvig et al., 7,018,847.

Vishnoi et al. has been discussed above. However, Vishnoi et al. do not disclose a buffer part for buffering the volumetric alteration at the time of loading raw liquid.

However, this is taught by Mendel-Hartvig et al. It is disclosed by Mendel-Hartvig et al. a membrane strip on a polyester backing, a sample filter with a blood cell/plasma separation membrane, and a buffer pad containing buffer. See column 8, lines 57-65. It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide a buffer pad as disclosed by Mendel-Hartvig et al. along with the plasma separation membrane of Vishnoi et al. because Mendel-Hartvig et al. disclose that this is a known technique employed with a blood cell/plasma separation

membrane. The skilled artisan would have recognized the benefits of providing a buffer for maintaining the desired pH.

Claims 10 and 11 are being unpatentable over Vishnoi et al. , 6,348,156, in view of Mendel-Hartvig et al., 7,018,847, as applied to claim 8 above, and further in view of Leader et al., 6,193,864.

Vishnoi et al. and Mendel-Hartvig et al. have been discussed above. However, neither patents disclose a flow pump that is a tube with a rotating rotor and a roller installed in a rotating manner in the outer circumference of the rotor and a portion of the outer wall of the device or cartridge is a squeezing member for squeezing a part of the flow channels of the circuit, as recited in claim 10. These limitations however are disclosed by Leader et al. as discussed further below.

It is noted however that Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprising positive and negative pneumatic pressure. Other types of fluid pressure can be used. See col. 8, lines 9-16. Figure 6 shows, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36 (see FIG. 1). The cassette 28 is, in

use, mounted in the pump and valve station 30. The pump and valve station 30 apply positive and negative pneumatic pressure upon the cassette 28 to direct liquid flow through the circuit. See column 8, lines 17-23. Figure 22 also shows, each actuator PA1 to PA4 and VA1 to VA23 includes a port 228. The ports 228 convey positive or negative pneumatic pressures from the source in a sequence governed by the controller 16. These positive and negative pressure pulses flex the front diaphragm 194 to operate the pump chambers PP1 to PP4 and valve stations V1 to V23 in the cassette 28. This, in turn, moves blood and processing liquid through the cassette 28. See col. 12, lines 16-29.

Moreover, Leader et al. disclose a cartridge for analyzing blood wherein the device includes a peristaltic roller pump for pumping fluids. The peristaltic roller pump includes a roller 206 that massages the pump tube 136. The roller 206 applies areas of alternating greater and lesser pressure to the pump tube 136, causing those portions of the pump tube 136 that lie over an area of greater pressure to be internally constricted and those areas of the pump tube 136 that lie over an area of lesser pressure to be relaxed to essentially the full unstressed diameter of the channel through the interior of the pump tube 136. As the roller 206 rotates, the areas of alternating greater and lesser pressure traverse the pump tube 136 to generate a peristaltic action in the pump tube 136. See column 8, lines 31-44.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide the peristaltic roller pump as disclosed by Leader et al. because Vishnoi et al. do not limit the type of pump that can be used and thus it would

have been obvious to the skilled artisan to look to the art for the various suitable pumping mechanisms, such as that disclosed by Leader et al., and modify the Vishnoi et al. device accordingly for incorporating the pumping mechanism.

As to claim 11, it is inherent that there is a mechanism in the Leader et al. device for transporting the Leader et al. cartridge in the direction to and from a rotor of the roller tube pump to squeeze a flow pipe, otherwise the tube will constantly be squeezed/stressed by the roller, which would not achieve the purposes of the pump as discussed by Leader et al.

Claims 13 and 14 are rejected being unpatentable over Vishnoi et al. , 6,348,156, in view of Leader et al., 6,193,864.

Vishnoi et al. has been discussed above (see discussion of claim 1 above) and are equally applicable here. However, Vishnoi et al. do not disclose a roller pump and a squeezing member for squeezing the tube of the roller tube pump. These limitations however are disclosed by Leader et al. as discussed further below.

It is noted however that Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprising positive and negative pneumatic pressure. Other types of fluid pressure can be used. See col. 8, lines 9-16. Figure 6

shows, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36 (see FIG. 1). The cassette 28 is, in use, mounted in the pump and valve station 30. The pump and valve station 30 apply positive and negative pneumatic pressure upon the cassette 28 to direct liquid flow through the circuit. See column 8, lines 17-23. Figure 22 also shows, each actuator PA1 to PA4 and VA1 to VA23 includes a port 228. The ports 228 convey positive or negative pneumatic pressures from the source in a sequence governed by the controller 16. These positive and negative pressure pulses flex the front diaphragm 194 to operate the pump chambers PP1 to PP4 and valve stations V1 to V23 in the cassette 28. This, in turn, moves blood and processing liquid through the cassette 28. See col. 12, lines 16-29.

Moreover, Leader et al. disclose a cartridge for analyzing blood wherein the device includes a peristaltic roller pump for pumping fluids. The peristaltic roller pump includes a roller 206 that massages the pump tube 136. The roller 206 applies areas of alternating greater and lesser pressure to the pump tube 136, causing those portions of the pump tube 136 that lie over an area of greater pressure to be internally constricted and those areas of the pump tube 136 that lie over an area of lesser pressure to be relaxed to essentially the full unstressed diameter of the channel through the interior of the pump tube 136. As the roller 206 rotates, the areas of alternating greater and lesser pressure traverse the pump tube 136 to generate a peristaltic action in the pump tube 136. See column 8, lines 31-44.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide the peristaltic roller pump as disclosed by Leader et al. because Vishnoi et al. do not limit the type of pump that can be used and thus it would have been obvious to the skilled artisan to look to the art for the various suitable pumping mechanisms, such as that disclosed by Leader et al., and modify the Vishnoi et al. device accordingly for incorporating the pumping mechanism.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komatsu et al., 5,976,433, in view of Anderson et al., 5,186,824.

Komatsu et al. disclose slit-like micropores mean micropores thinly extending in the direction of hollow fiber axis (col. 3, lines 24-33.) The PVA-based hollow fiber membranes, having sharp fractionating capability, is effective in separating different substances having close particle sizes and can be used for blood filtration, among other uses (col. 6, lines 53-61.)

However, as to claims 24-26, Komatsu et al. do not disclose that the solution to be fractionated contains an organic solvent, specifically acetonitrile, nor in the percent volume range recited by Applicant.

Anderson et al. however teach that reagents diffuse into and out of pores and interstices of solid phase particles at rates which depend on both the particle and pore sizes, the temperature of the molecular weights of the solutes, and the viscosity of the

solvent and are never instantaneous (column 4, lines 1-23.) Anderson et al. also disclose that acetonitrile is a common solvent used for separations (column 23, lines 42-67.) It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide acetonitrile as a solvent in using the Komatsu et al. membrane filtration since acetonitrile is a common solvent for biological separations, as shown by Anderson et al.

Likewise, as to the range in temperature as recited in claim 27, this range is within a workable range and thus its discovery requires only routine skills in the art.

Allowable Subject Matter

Claims 15-23 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Examiner, Art Unit 1641